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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,972	05/11/2001	BARRY ROSS MATTHEWS	017227/0171	7954

7590 11/30/2005

Foley & Lardner  
Washington Harbour  
Suite 500  
3000 K Street  
Washington, DC 20007-5109

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/786,972		MATTHEWS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Blessing M. Fubara		1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for reconsideration and remarks filed 09/16/05. Claims 1-11 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. Claims 1-11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et al. (WO 95/34595).

Applicants argue:

a) The interpretation of the claims by the office is unfounded because “claim language takes its plain and ordinary meaning unless the specification, including figures, clearly conveys another meaning. *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 69 USPQ2d 1857 (Fed. Cir. 2004).

b) The specification does not validate the office contention that toxic materials embrace the actual virus and that the record is devoid of any indication that a skilled artisan would equate virus with toxin.

c) The commentary on page 9 of the specification qualifies toxin by reference to the origin.

2. Applicants' arguments filed 09/16/05 with respect to b) have been fully considered and found persuasive because examiner notes that toxic materials do not embrace the actual virus and the skilled artisan would know that virus can produce toxic materials.

3. Applicants' arguments filed 09/16/05 with respect to a) and c) have been fully considered but they are not persuasive.

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Amended claim 1 (amendment of 12/14/04) selects toxic material from the group consisting of “(i) toxins and toxic peptides of biological origin and (ii) toxins and toxic peptides released during bacterial, protozoal or fungal infection.” The toxic material can therefore be toxins and toxic peptides of biological origin. A virus is of biological origin. Toxin in a broad interpretation is capable of inducing antibody formation. HIV infection induces the formation of antibodies. Secondly, applicants in the remarks at lines 1 and 2 of page 3, indicate that HIV is the origin of Vpr peptide fraction P3. Since as per applicants, page 9 of the instant specification, qualifies toxins by reference to origin, it is noted that this statement further supports HIV, a biological material as producing toxins or may originate toxins.

#### ***Double Patenting***

4. Claims 1-11 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36, 38 and 39 of U.S. Patent No. 6,190,650.

Applicants argue that US 6,190,650 fails to treat infections caused by toxins and that the evidence on record fails to show that toxic material or substance can be construed as a viral infection.

5. Applicants' arguments filed 09/16/05 have been fully considered but they are not persuasive.

HIV is of a biological origin and produces toxins. In this case, claim 38 of the reference prophylactically or therapeutically treats viral infection in human or non-human with the composition of claim 1. Claim 1 of the reference encompasses claim 7 of the application. The application for the most part recites a method of inhibiting toxic material where the toxic material is a viral infection (claims 1 and 12) and the method comprises administering an

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effective amount of a dendrimer to a patient in need thereof. The issued patent for the most part teaches a dendrimer composition and a method for administering the composition to treat the same conditions or infections that are caused by toxins. Treating or treatment encompasses inhibiting. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of the issued patent. One having ordinary skill in the art would have been motivated to administer the composition of the issued patent to a patient in need thereof with the expectation that the composition would treat or inhibit activity of the toxic material or substance released from viral infection.

No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

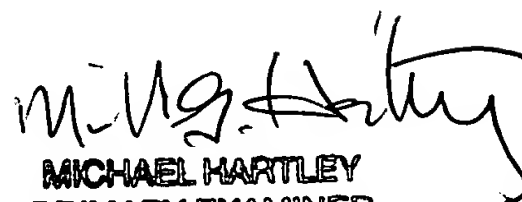
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MICHAEL HARTLEY  
PRIMARY EXAMINER